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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,635	08/02/2006	Uyen K. Tran	071949-9701	7561

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
11/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,635	TRAN ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *120-137* is/are pending in the application.

4a) Of the above claim(s) *120-126 and 135-137* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *127-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2806, 11/8/06, 11/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence alignments*.

DETAILED ACTION

1. Applicant's response received August 14, 2008 is acknowledged.

Claims 1-119 have been canceled.
Claims 120-137 are pending in the instant application.

Applicant's election without traverse of Group II, claims 127-134, drawn to antibodies in the reply filed on August 14, 2008 is acknowledged.

Claims 120-126 and 135-137 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 14, 2008.

Claims 127-134 are under expression as thy read on antibodies that bind an amino acid sequence of SEQ ID NO:3

Information Disclosure Statement

2. The IDS forms received 10/28/06, 11/8/06, and 11/16/06 are acknowledged and have been considered.

Specification

3. The title and abstract are objected to for not specifying the instant claimed subject matter. Submission of a new title and abstract that better reflect the subject matter of the elected invention is suggested.

Claim Objections

4. Claims 127-134 are objected to as being dependent, either directly or indirectly, upon withdrawn claims. It is suggested that claims 127 and 131 should be rewritten in

independent form and be amended to incorporate all of the limitations recited in the withdrawn claim. Other claim amendments are also possible to correct the dependency problem.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 127-134 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant has claimed a genus of antibodies that bind to polypeptides comprising a sequence of SEQ ID NO:3. Thus the claimed genus encompasses antibodies that bind a subsequence of SEQ ID NO:3 when said subsequence is present in isolation or as part of a longer sequence that is heterologous to SEQ ID NO:3. No working examples wherein antibodies that bind to SEQ ID NO:3 or a fragment thereof appear to be present in the specification. The disclosure asserts that the data presented in Tables 2 and 3 establishes that SEQ ID NO:3 is an immune response protein. The data of Table 2 indicate that SEQ ID NO:3 is most similar to the human IL-22 receptor. The data of Table 3 indicate that SEQ ID NO:3 comprises a signal peptide, putative phosphorylation sites, and putative glycosylation sites. No data appears to be presented indicating that the polypeptide of SEQ ID NO:3 was ever isolated from tissue or synthesized. Instead, it appears that the polypeptide of SEQ ID NO:3 is the predicted translation product of the polynucleotide of SEQ ID NO:35. No data appears to be presented that the polynucleotide of SEQ ID NO:35 is actually translated into a polypeptide sequence in vivo, and data indicating that SEQ ID NO:35 is differentially expressed in one or more disease states also appears to be lacking. As such, it appears that applicant has based the assertion that the polypeptide of SEQ ID NO:3 is useful because it comprises sequence homology with the human IL-22 receptor.

However, no data is present to indicate that SEQ ID NO:3 functions in any manner similar to that of the IL-22 receptor, such as in its ability to bind IL-22, and it is known in the art that not all transcribed polynucleotides are translated into polypeptides.

Skolnick et al. (Trends in Biotechnology, 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see particularly the Abstract and the section titled Sequence-based approaches to function prediction on page 34). Even in situations where there is some confidence of a similar overall structure between two sequences, only experimental research can confirm the artisan's best guess as to the function of the structurally related sequence (see in particular the Abstract and Box 2 on page 36). The complexity of the problem of assigning function based on homology rises as the percent similarity or identity falls (see Whisstock et al., Quarterly Reviews of Biophysics, 2003, 36:307-340, particularly the sentence that spans pages 321 and 323). Given that neither the specification nor the prior art clearly indicate the structural region of the polypeptide of SEQ ID NO:3 that are required for biological activity, or disclose biological activities that are specific to the polypeptide of SEQ ID NO:3, a skilled artisan would not know to use the polypeptide of SEQ ID NO:3. Specifically, is the polypeptide of SEQ ID NO:3 ever actually expressed in vivo, and if so, what does it do? Thus, the specification fails to disclose a specific and substantial utility for the polypeptide of SEQ ID NO:3. Logically, if the polypeptide of SEQ ID NO:3 does not have a specific or substantial utility, antibodies that bind the polypeptide of SEQ ID NO:3 also lack a specific and substantial utility.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 127-134 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 127-134 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,965,704 as evidenced by Kuby (Immunology, 1991, W.H. Freeman and Company, page 125).

The '704 patent discloses antibodies that bind a polypeptide disclosed as Zcytor11 (see entire document, particularly column 15). These antibodies are disclosed as being polyclonal, monoclonal, single chain antibodies, and Fab fragments (see particularly lines 13-20 of column 15). Zcytor11 is 84% identical to SEQ ID NO:3 of the instant invention, with a stretch of 100% identity spanning 118 amino acids (see attached sequence alignment). Note that SEQ ID NO:3 of the instant invention is only 142 amino acids in length. Further note that the claimed genus of antibodies encompasses those that bind a fragment of SEQ ID NO:3, including when said fragment of SEQ ID NO:3 is part of a larger polypeptide sequence. As evidenced by Kuby,

crossreactivity is a widespread phenomenon in the antibody art, occurring when antibodies recognize the same or structurally similar epitopes in distinct antigens. As stated earlier, Zcytor11 and SEQ ID NO:3 share a 118 amino acid epitope of 100% identity, and thus antibodies that bind Zcytor11 are expected to bind SEQ ID NO:3 since Zcytor11 comprises an amino acid sequence of SEQ ID NO:3.

Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

It is noted that the antibodies of the '705 patent are not disclosed as having been made by screening a recombinant immunoglobulin or Fab expression library. Applicant is reminded that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Therefore, the prior art anticipates the claimed invention.

11. Claims 127-134 are rejected under 35 U.S.C. 102(a and e) as being anticipated by WO 02/18424 A2 as evidenced by Kuby (Immunology, 1991, W.H. Freeman and Company, page 125).

The '424 patent discloses antibodies that bind novel polypeptides (see entire document, particularly page 1). One particular polypeptide is disclosed as being 86% identical to the IL-22 receptor (see SEQ ID NO:430 on page 110). This same

polypeptide is 142 amino acids in length, is 99.2% identical to SEQ ID NO:3 of the instant application, and differs from SEQ ID NO:3 of the instant invention by only one amino acid residue (see enclosed sequence alignment). Antibodies of the '424 patent are disclosed as being polyclonal, monoclonal, single chain antibodies, Fab fragments, and other forms, many of which are identified by screening various recombinant expression libraries (see particularly pages 74-83). As evidenced by Kuby, crossreactivity is a widespread phenomenon in the antibody art, occurring when antibodies recognize the same or structurally similar epitopes in distinct antigens. Given that there is only one amino acid difference between the prior art polypeptide and SEQ ID NO:3, the prior art antibodies will bind SEQ ID NO:3.

Applicant is reminded that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Therefore, the prior art anticipates the claimed invention.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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